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Amarin Announces Publication of REDUCE-IT Cardiovascular Outcomes Study Rationale and Design in Clinical Cardiology

BEDMINSTER, N.J. and DUBLIN, Ireland, March 15, 2017 (GLOBE NEWSWIRE) -- Amarin Corporation plc (NASDAQ:AMRN) announced the publication today of the rationale and design for the company's REDUCE-IT Phase 3 cardiovascular outcomes study in *Clinical Cardiology*, available at: http://onlinelibrary.wiley.com/doi/10.1002/clc.22692/full.

Deepak L. Bhatt, M.D., M.P.H., executive director of the Interventional Cardiovascular Programs at Brigham and Women's Hospital, professor of medicine, Harvard Medical School in Boston, Mass., is the lead author of the published article titled, "Rationale and Design of REDUCE-IT: Reduction of Cardiovascular Events with Icosapent Ethyl - Intervention Trial."

REDUCE-IT is a landmark global study of approximately 8,000 patients to evaluate whether treatment with prescription pure EPA Vascepa® (icosapent ethyl) at four grams per day reduces cardiovascular events in patients, who despite having their LDL-cholesterol (LDL-C) controlled with statin therapy, have elevated triglyceride levels and demonstrate other risk factors, such as diabetes and previous cardiovascular events.

"Controlling LDL-C is critically important but only one aspect of overall good cardiovascular health," said Dr. Bhatt. "The risk of cardiovascular events remains high due to independent factors that cannot be addressed only by reducing LDL-C. The question of how best to achieve cardiovascular risk reduction beyond the benefits realized from effective management of LDL-C remains unanswered. The REDUCE-IT trial is designed to address whether the demonstrated clinical effects and postulated pleiotropic cardioprotective benefits of icosapent ethyl when added to statin therapy will offer improved cardiovascular outcomes for patients and provide physicians with a new treatment option in the studied high cardiovascular risk population."

The publication notes that, while clinical and epidemiological studies have demonstrated patients with elevated triglycerides remain at high cardiovascular risk despite controlling LDL-C, to date no study has prospectively examined this population. For this population, high dose prescription pure EPA may prove beneficial. EPA has been shown to improve relevant lipid, lipoprotein and inflammatory parameters without raising LDL-C and may have pleiotropic benefits. An open label, blinded endpoint outcomes study in Japan of low doses of prescription pure EPA added to statin therapies has been shown to produce further cardiovascular event reduction with moderately elevated triglycerides, by 19% in the overall population and by 53% in a subgroup of patients similar to those enrolled in the REDUCE-IT study. REDUCE-IT is evaluating whether treatment with high dose EPA reduces ischemic events in statin-treated patients with persistent elevated triglycerides.

"Despite significant advances in the diagnosis, management, and understanding of cardiovascular disease, it remains the leading killer in this country," said Steven B. Ketchum, Ph.D., president of R&D and chief scientific officer of Amarin. "We are confident that REDUCE-IT will provide important answers on whether the addition of prescription pure EPA Vascepa to patients with persistent elevated triglycerides after statin therapy confers a meaningful reduction in the occurrence of major cardiovascular events in this high-risk patient population."

Residual Cardiovascular Risk in Statin-Treated Patients

Cardiovascular disease remains the leading cause of death in the United States, with the estimated costs of treating heart attacks, strokes and other cardiovascular diseases exceeding $300 billion annually. In the United States, more than 35 million patients are treated with statins for the primary and secondary prevention of atherosclerotic cardiovascular events, including myocardial infarctions (heart attacks), and stroke. Despite the demonstrated clinical benefits of lowering LDL-C with statins, significant residual cardiovascular risk remains for statin-treated patients. Vascepa is being studied in REDUCE-IT as an add-on to statin therapy to further reduce cardiovascular risk, not as a replacement for statin therapy.

About REDUCE-IT

REDUCE-IT is a global Phase 3, randomized, multicenter, double-blind, placebo-controlled study designed to evaluate whether treatment with Vascepa reduces cardiovascular events in patients who despite stabilized statin therapy have elevated triglyceride levels and other cardiovascular risk factors. The primary endpoint of the study is the time to the first occurrence of the composite endpoint of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or hospitalization for unstable angina. Secondary endpoints include time to event analyses of components of the primary endpoint. The study is being conducted under a special protocol assessment agreement with the FDA.

Additional information on the REDUCE-IT trial and Amarin's other clinical studies of Vascepa can be found at www.clinicaltrials.gov.

About Vascepa® (icosapent ethyl) capsules

Vascepa® (icosapent ethyl) capsules are a single-molecule prescription product consisting of the omega-3 acid commonly known as EPA in ethyl-ester form. Vascepa is not fish oil, but is derived from fish through a stringent and complex FDA-regulated manufacturing process designed to effectively eliminate impurities and isolate and protect the single molecule active ingredient. Vascepa is known in scientific literature as AMR101.

FDA-approved Indication and Usage

- Vascepa (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.
- The effect of Vascepa on the risk for pancreatitis and cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Important Safety Information for Vascepa

- Vascepa is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to Vascepa or any of its components.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- The most common reported adverse reaction (incidence > 2% and greater than placebo) was arthralgia (2.3% for Vascepa, 1.0% for placebo). There was no reported adverse reaction > 3% and greater than placebo.
- Patients receiving treatment with Vascepa and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Patients should be advised to swallow Vascepa capsules whole; not to break open, crush, dissolve, or chew Vascepa.
- Adverse events and product complaints may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

FULL VASCEPA PRESCRIBING INFORMATION CAN BE FOUND AT WWW.VASCEPA.COM.

Vascepa has been approved for use by the United States Food and Drug Administration (FDA) as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia. Vascepa is under various stages of development for potential use in other indications that have not been approved by the FDA. Nothing in this press release should be construed as promoting the use of Vascepa in any indication that has not been approved by the FDA.

About Amarin

Amarin Corporation plc is a biopharmaceutical company focused on the commercialization and development of therapeutics to improve cardiovascular health. Amarin's product development program leverages its extensive experience in lipid science and the potential therapeutic benefits of polyunsaturated fatty acids. Amarin's clinical program includes a commitment to the ongoing REDUCE-IT cardiovascular outcomes study. Vascepa® (icosapent ethyl), Amarin's first FDA-approved product, is a highly-pure, EPA-only, omega-3 fatty acid product available by prescription. For more information about Vascepa, visit www.vascepa.com. For more information about Amarin, visit www.amarincorp.com.

Forward-looking statements

This press release contains forward-looking statements such as expectations regarding the ability of REDUCE-IT to provide important answers on whether the addition of Vascepa to statin therapy would confer a meaningful reduction in the occurrence of major cardiovascular events in the patient population studied. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. For example, statements related to the potential efficacy and therapeutic benefits of Vascepa have been subject to different interpretations on matters such as the potential clinical importance of lowering triglyceride levels in studied patients. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with complex clinical trials like REDUCE-IT and research and development and clinical trial risk generally; differing views on interpretation of clinical trial results including the results of the cited Japanese study and other relevant studies; and reliance on third parties.

Due to these risks and other uncertainties, REDUCE-IT may not generate positive or useful results. A further list and description of these risks, uncertainties and other risks associated with an investment in Amarin can be found in Amarin's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Amarin undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

Availability of other information about Amarin

Investors and others should note that we communicate with our investors and the public using our company website (www.amarincorp.com), our investor relations website (http://investor.amarincorp.com), including but not limited to investor presentations and investor FAQs, Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that we post on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in Amarin to review the information that we post on these channels, including our investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

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